K113869

JUL 26 2012

510(k) SUMMARY

Submitter:	OriGen Biomedical, Inc 7000 Burleson Rd, Bldg D Austin, TX 78744
Contact Person:	Richard Martin Phone +1 512 474 7278 dmartin@origen.com
Date Prepared:	25 July 2012
Device Trade Name:	OriGen Reinforced Dual Lumen cannula
Common Names:	ECMO catheter ECLS catheter Veno-Venous catheter
Classification Names:	Catheter, vascular access
Predicate Device:	OriGen Dual Lumen cannula

Device Description:
The OriGen Reinforced Dual Lumen catheter (RDLC) is the same design as the OriGen Dual Lumen Catheter (the predicate device), but with the addition of a wire reinforcement layer on the tip of the device. Both are dual lumen catheters with unequal lumen areas for drainage and re-infusion. A thin sheath is used to cover and secure the wire layer and is heat shrunk into a permanent position. Other characteristics of the catheter are the same.

Indications for Use:
The OriGen RDLC catheter is indicated for use as a single cannula for both venous drainage and arterial re-infusion of blood in the internal jugular vein during extracorporeal life support procedures of six hours or less.

Technological Characteristics:
The OriGen RDLC catheter has the same fundamental technological characteristics, principles of operation and manufacturing processes as the predicate device. The new device has an added wire reinforcement layer and a smooth protective sheath over that. This extra material adds approximately 1 French size over the existing catheter diameter. However, the polyurethane material of the original OriGen Dual Lumen Catheter was not compatible with this process and Pebax is now used. Pebax has excellent biocompatibility and a long history of use in medical applications in catheters and central lines.

As the internal geometry and manufacturing practices have not changed, the flow characteristics of the device are unchanged.

Non Clinical Test Results:
Applicable tests were carried out in accordance with the requirements of ISO 10993-1 and the FDA 1995 memorandum on the use of that standard for biocompatibility testing of materials.

In Vitro Test Results:
In vitro testing was carried out to demonstrate both substantial equivalence with the predicate device and to demonstrate the safety and effectiveness of the new catheter test results supplied in the 510(k) premarket notification include performance and mechanical integrity tests which all demonstrated both safety and effectiveness. The tests which were performed are listed in the following summarizing table:

Test Classification - Title	**Test results**
Physical /mechanical - structural integrity	Pass
Physical /mechanical - burst testing	Pass
Physical /mechanical - kink testing	Pass
Functional/Performance - flow testing	Pass

Conclusions:
The results of the *in vitro* studies demonstrate that the Origen Dual Lumen Reinforced Catheter performs in a manner substantially equivalent to the predicate device, the Origen Dual Lumen Catheter. Test results of this study demonstrate that the two devices function with substantially equivalent performance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JUL 26 2012

Origen Biomedical
c/o Mr. Richard Martin
President
7000 Burleson Road, Building D
Austin, TX 78744

Re: K113869
Trade/Device Name: Origen Reinforced Dual Lumen Catheter
Regulation Number: 21 CFR 870.1300
Regulation Name: Catheter cannula
Regulatory Class: Class II
Product Code: DWF
Dated: July 24, 2012
Received: July 25, 2012

Dear Mr. Martin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510 (k) NUMBER (IF KNOWN) : K113869

DEVICE NAME : OriGen Reinforced Dual Lumen Cannula

INDICATIONS FOR USE :

The OriGen Reinforced Dual Lumen Cannula is indicated for use as a single cannula for both venous drainage and arterial re-infusion of blood in the internal jugular vein during extracorporeal life support procedures of six hours or less.

Prescription Use _____ OR Over-The-Counter-Use _____
(Per 21 CFR 801.109) (Optional Format 1-2-96)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K113869